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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,417	07/01/2003	Denis Leclerc	1398-104US	9472
50438 7590 04/02/2007 JUNEAU PARTNERS P.O. BOX 2516 ALEXANDRIA, VA 22301			EXAMINER BOESEN, AGNIESZKA	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/609,417

Applicant(s)

LECLERC ET AL.

Examiner

Agnieszka Boesen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-25 and 27-54 is/are pending in the application.
- 4a) Of the above claim(s) 31,40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25, 27-30, 32-39, 42-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2007 has been entered.

New claims 45-54 have been added. Claims 20-25, 27-30, 32-39 and 42-54 are under consideration in the present Office Action.

Claim Rejections - 35 USC § 112

Rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention with regard to recitation of the phrase "derived" is **withdrawn** in view of Applicant's amendment.

Rejection of claims 20-25, 27-30, 32-39, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** in view of Applicant's amendment and arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-24, 25, 27-30, 32-35, 38, 39, 42-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee-Shanok (Construction and preliminary characterization of papaya mosaic virus as an expression vector for the presentation of foreign epitopes, Thesis for Degree of Master of Science, University of Toronto, 1999).

Claims are drawn to a method of potentiating an immune response against an antigen comprising B-cell antigenic and/or T-cell antigenic epitopes, the method comprising the step of administering to an animal an antigen and an effective amount of an adjuvant, wherein said adjuvant is a papaya mosaic virus (PapMV) or a virus-like particle comprising PapMV coat protein or modified PapMV coat protein. The PapMv is a wild type virus, a recombinant virus, and a pseudovirus. The antigen, specifically the hepatitis C virus antigenic epitope is covalently attached to PapMV or VLP, the PapMV or VLP and the antigen are not linked. The antigen together with the PapMV adjuvant are administered orally. The immune response is a humoral and a cellular immune response. With regard to the limitation of pseudoviruses the current specification discloses that pseudoviruses are included in the papaya mosaic virus VLP. Without specific definition in the current specification with regard to pseudoviruses it is understood that pseudoviruses are encompassed within the claimed modified papaya mosaic virus VLPs.

Lee-Shanok discloses a method of potentiating an immune response against antigenic epitopes, specifically HCV epitopes recombinantly engineered to be expressed by papaya mosaic virus particles (see the entire document, particularly the Results on pages 52, 55-58, 72, and Figure 5). The papaya mosaic virus disclosed by Lee-Shanok has been modified (see Abstract

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and Results). Lee-Shanok discloses purified wild-type papaya mosaic virus particles (see pages 83-84 and Figure 16). The HCV antigens disclosed by Lee-Shanok are fused to the capsid protein of the papaya mosaic virus particles (see Results page 52).

Lee-Shanok discloses attachment of antigens to the coat protein of the papaya mosaic virus particles (see page 90). Lee-Shanok does not expressly recite that the antigens are covalently attached to the coat protein of the papaya mosaic virus particles, however since the reference discloses the fusion and attachment of the antigen(s) to the capsid protein, one expects the bond between the antigen and the capsid to be a covalent bond. Unless the two molecules are covalently linked the two molecules would not have been attached one to another. Thus Lee-Shanok anticipates the limitation of "covalently attached". Lee-Shanok discloses the papaya mosaic virus VLPs without the antigen, and the antigen not linked to the papaya mosaic virus VLPs (see Abstract and Figure 16A).

Lee-Shanok discloses oral administration of the papaya mosaic virus particles fused with the HCV epitope (see page 91). Lee-Shanok does not specify what kind of immune responses are generated due to administration of papaya mosaic virus particles fused with the HCV nucleocapsid gene, however Lee-Shanok discloses that papaya mosaic virus particles fused with the HCV nucleocapsid gene can be used as a vaccine (see pages 90-92). Because Lee-Shanok broadly refers to the immune responses, it is expected that humoral and cellular immune responses are generated in the method disclosed by Lee-Shanok.

Because Lee-Shanok discloses the subject matter and the limitations of the current claims, Lee-Shanok anticipates the current invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee-Shanok (Construction and preliminary characterization of papaya mosaic virus as an expression vector for the presentation of foreign epitopes, Thesis for Degree of Master of Science, University of Toronto, 1999) as applied to claim 20 above.

Claims are drawn to a method comprising the step of administering to an animal an antigen and an effective amount of an adjuvant, wherein said adjuvant is a papaya mosaic virus (PapMV) or a virus-like particle comprising PapMV coat protein or modified PapMV coat protein. The adjuvant is administered to an animal prior to administration of the antigen and the adjuvant is administered subsequent to administration of the antigen.

Lee-Shanok anticipates the claimed method as discussed above, Lee-Shanok does not teach particular immunization schedule currently claimed, however it would have been well within the knowledge and ability of the ordinary artisan to implement various immunization schedules including changing the order of antigen versus adjuvant being administered. One of ordinary skill would have been motivated to administer an adjuvant prior to administration of an antigen and vice-versa for the purpose of optimizing the immunization effect. Thus the current

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invention is unpatentable as being obvious over the prior art and the general knowledge in the art of vaccine development.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

3/28/07

Stacy B. Chen 3/29/07
STACY B. CHEN
PRIMARY EXAMINER